

REMARKS

In the Office Communication dated February 1, 2011, the Examiner states that claims 147-166, added in the reply filed on November 23, 2010, are “not readable on the elected invention.” The Examiner further states that the elected invention is drawn to “a specific immunization protocol, i.e., mucosal administration of an antigen and a CpG, followed by boosting with a CpG via any route.”

Applicant hereby respectfully traverses the restriction between new claims 147-166 and the previously pending claims for the reasons set forth below.

First, the Examiner has mischaracterized the elected invention, and in doing so has incorrectly concluded that new claims 147-166 are not readable on the elected invention. The restriction requirement dated January 30, 2001 set forth twelve different inventions (Groups I-XII). In response, Applicant elected Group I (original claims 1-28) drawn to

“a combination immunization method of employing an oligonucleotide and an antigen for inducing an (sic) mucosal immunity in a subject, wherein the oligonucleotide sequence has the following formula: 5' X₁X₂GCX₃X₄3' wherein C and G are unmethylated, wherein X₁, X₂, X₃ and X₄ are nucleotides, and wherein the antigen is not encoded in a nucleic acid vector.” (Page 2 of the Restriction Requirement.)

Claim 1, as pending at that time, recited

“A method for inducing a mucosal immune response, comprising:
administering to a mucosal surface of a subject an effective amount for inducing a mucosal immune response of an oligonucleotide, having a sequence including at least the following formula:



wherein C and G are unmethylated, wherein X₁, X₂, X₃, and X₄ are nucleotides, and exposing the subject to an antigen to induce the mucosal immune response, and wherein the antigen is not encoded in a nucleic acid vector.”

Moreover, claim 1 as pending prior to the reply filed on November 23, 2010 recited

“A method for inducing a mucosal immune response, comprising:
administering to a subject in need of a mucosal immune response an effective amount for inducing a mucosal immune response of an oligonucleotide 8 to 100 nucleotides in length, having a sequence including at least the following formula:



wherein C is unmethylated, wherein X₁, X₂, X₃, and X₄ are nucleotides, and an antigen,

wherein the antigen is not encoded in a nucleic acid vector, the oligonucleotide and the antigen are both administered vaginally, rectally, intranasally, ocularly, or by inhalation to the subject, a cytokine and an immune stimulating complex are not administered to the subject, and the antigen is not a *Streptococcus pneumoniae* antigen.”

There is no recitation of a boosting limitation in the description of Group I, nor in claim 1 as it was pending at the time of the restriction, nor in claim 1 as it was last pending. Also, none of these recited that antigen could not be administered before or after mucosal administration of antigen and oligonucleotide.

Moreover, none of the other Groups in the restriction requirement recites a boosting limitation, nor is any of these other Groups restricted to a particular order of administration of the antigen and the oligonucleotide.

Accordingly, there is nothing in the record that supports the Examiner’s characterization of the elected invention. The elected invention is as stated in the restriction, and new claim 147-166 are readable thereon.

Second, the Examiner has not met her burden regarding restriction between new claims 147-166 and previously pending claims 1-146. In particular, as set forth in MPEP 803(I), in order for restriction between two inventions to be proper, the Examiner must establish that there would be a serious burden if restriction were not required. The Examiner not asserted that a serious burden would exist and has not provided any evidence of such burden as required by MPEP 808 (“Every requirement to restrict has two aspects: ... (B) the reasons why there would be a serious burden on the examiner if restriction is not required ...”).

For these reasons, Applicant requests reconsideration of the restriction between claims 147-166 and previously pending claims 1-146. Applicant further reserves the right to file a petition from the requirement for restriction.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. C1040.70006US00.

Respectfully submitted,

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